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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/185,732    11/04/98    BARROWS    T    09125/001001

HM12/1024

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EXAMINER

RUSSEL, J

ART UNIT

PAPER NUMBER

1653

27.

DATE MAILED:

10/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/185732

Applicant(s)

T. Barrows et al

Examiner

J. Russell

Group Art Unit

1653

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

☒ Responsive to communication(s) filed on 9-9-2001

☒ This action is **FINAL**.

- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

☒ Claim(s) 1-440 is/are pending in the application.

Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☒ Claim(s) 1-17 and 163-299 is/are allowed.

☒ Claim(s) 18-162 and 300-440 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 26
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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1. The consent of assignee to the reissue and the offer to surrender have been received.

The request for transfer of original drawings has been received. This request will be treated as a request to transfer the formal drawings from the original patent file to the reissue application. See MPEP 1413.

The copy of the Certificate of Correction correcting the inventorship of the application has been received.

The corrected copy of the page of the specification corresponding to column 3 of the patent has been received and entered.

The supplemental declaration by Barrows filed October 14, 1999 (a copy of which was attached to the response filed June 30, 2000) in combination with the supplemental reissue oath/declaration filed September 30, 1999 satisfies the requirement under 37 CFR 1.175 for a reissue oath or declaration.

Applicant is reminded of the continuing obligation under 37 CFR 1.56 to timely apprise the Office of any litigation information, or other prior or concurrent proceeding, involving Patent No. 5,583,114, which is material to patentability of the claims under consideration in this reissue application. This obligation rests with each individual associated with the filing and prosecution of this application for reissue. See MPEP §§ 1404, 1442.01 and 1442.04.

2. Claims 18-162 and 300-440 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46

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USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984).

A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

(a) Claims 18-162 are broader in scope than the patented method claims in terms of the protein, protein concentration, crosslinking agent concentration, and burst strength limitation. Claims 300-440 are broader in scope than the patented method claims in terms of protein and burst strength limitation. In particular, the patented method claims require the use of serum albumin, whereas new claims added in this reissue application permit the use of any albumin. The patented method claims require a protein concentration of about 20-60 wt/vol %, whereas new claims added in this reissue application permit the use of any concentration of protein. The patented method claims require a crosslinking agent concentration of about 50-800 mg/ml, whereas new claims added in this reissue application permit the use of any concentration of crosslinking agent. The patented method claims require a burst strength of greater than about 10 mmHg, whereas new claims added in this reissue application permit any burst strength.

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(b) These limitations were inserted into the claims eventually allowed in the patent by the amendment filed June 12, 1995 in order to overcome a prior art rejection. Further, the remarks accompanying the amendment filed June 12, 1995 (see, e.g., page 7, line 7, and page 8, lines 2-5) and the remarks filed January 24, 1996 (see, e.g., page 2, line 20, and page 3, lines 2-5) in response to another prior art rejection explicitly refer to the serum albumin and burst strength limitations as helping to distinguish over the prior art on the basis of a patentable difference in terms of composition and characteristics of the composition. In the absence of any other evidence, the making of an amendment to claims in response to prior art rejections permits an inference of surrender. See, e.g., MPEP 1412.02, Example (b). The remarks made by Applicants in conjunction with these amendments (which are in no manner analogous to the “boiler plate” remarks discussed in MPEP 1412.02, Example (A)) are further evidence of surrendered subject matter.

(c) At least one of these instances of surrendered subject matter is present in instant claims 18-162 and 300-440, although not all of the instances of surrendered subject matter occur in every claim. With respect to the protein identity, the independent reissue claims 18, 52, 84, 119, 300, 333, 364, and 398 (which recite “albumin”) are now broader in this aspect than originally-presented claim 2 (which recited “serum albumin”). With respect to protein concentration, independent reissue claims 18, 52, 84, and 119 do not recite any protein concentration and thus are as broad in this aspect as the broadest originally-presented claims, which also did not recite a protein concentration. With respect to crosslinking agent concentration, independent reissue

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claims 18, 52, 84, and 119 do not recite any crosslinking agent concentration and thus are as broad in this aspect as the broadest originally-presented claims, which also do not recite a crosslinking agent concentration. With respect to burst strength limitation, independent reissue claims 18, 52, 84, 119, 300, 333, 364, and 398 do not recite any burst strength limitation and thus are as broad in this aspect as any of the originally-presented claims (which did not include any burst strength limitation). Broadening the reissue claims with respect to these limitations therefore constitutes the recapture of surrendered subject matter and is improper.

3. The amendment filed September 4, 2001 contains amendments to claims 1, 15, and 17 that do not comply with 37 CFR 1.173, which set forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required.

In particular, amendments to the claims in the patent must be marked with respect to the claims as they occurred in the patent. See 37 CFR 1.173(d). For example, even though the word "mixture" was changed to "composition" in claim 15 in a previous amendment, the latest version must still show the word "mixture" enclosed by brackets and the word "composition" underlined. Again, as was noted in the previous Office action, the current version of amended claims 1, 15, and 17 still do not accurately reproduce the claims as they occurred in the patent and do not accurately mark all of the changes which have been made to the claims, especially with respect to punctuation and prepositions occurring within.

4. Applicant's arguments filed September 4, 2001 have been fully considered but they are not persuasive.

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The rejection of claims 18-162 and 300-440 under 35 U.S.C. 251 as being an improper recapture is maintained for the reasons of record. The recapture analysis does not confuse claim cancellation with subject matter surrender - see section (b) of the recapture analysis. The claim cancellation is analyzed in its context, i.e. as an attempt by Applicants to distinguish over a prior art rejection. See also the examiner's discussion of surrender in the previous Office action, beginning with the last paragraph of page 9 and continuing through page 11. The examiner also does not agree that the only issue under recapture is whether or not the claims in the reissue application are broader than the broadest independent claims examined in the parent application - see the examiner's discussion of Clement at page 12 of the previous Office action.

5. After the corrections specified in paragraph 3 above are made, claims 1-17 will be allowed. Claims 163-299 are allowed.
6. The references crossed off of the Information Disclosure Statement filed September 4, 2001 are duplicate citations.
7. The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

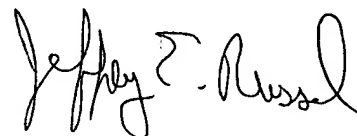
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Christopher Low can be reached at (703) 308-2923. The fax number for Art Unit 1653 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 305-7401 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel  
Primary Patent Examiner  
Art Unit 1653

JRussel  
October 22, 2001